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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,822	02/08/2002	Gregory E. Hardee	ISIS-4947	4141
34138	7590	09/07/2005	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			GIBBS, TERRA C	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,822

Applicant(s)

HARDEE ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a response to Applicants Amendment and Remarks filed July 6, 2005.

Claims 26 and 27 are pending in the instant applicaiton.

Claims 26 and 27 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In the previous Office Action mailed April 6, 2005, claims 26 and 27 were rejected under 35 U.S.C. 102(a) as being anticipated by Dean et al. [WO 98/49348]. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed April 6, 2005.

Response to Arguments

In response to this rejection, Applicants argue that Dean et al. does not anticipate the claims because claims 26 and 27 recite a multi-particulate formulation comprising a "plurality of carrier particles". Applicants contend that the instant specification at page 3-5 disclose examples of these carrier particles. Applicants argue that Dean et al. does

not teach or suggest a formulation comprising a plurality of carrier particles and thus does not anticipate the present claims.

Applicant's arguments have been fully considered but are not found persuasive because while the instant specification discloses examples of carrier particles, these examples are merely *preferred* but not *required* by the instant claims. Further, the Examiner disagrees that Dean et al. does not teach a "plurality of carrier particles" as argued.

The instant specification at page 3, paragraph [0010] discloses, "Carrier particles according to the present invention include a variety of particle-forming substances". The instant specification at page 3, paragraph [0010] also discloses, "Preferred carrier particles are those which enhance bioavailability of biologically active substance upon administration and delivery to a mucosal membrane". Dean et al. disclose at Table 1, compound 2302, when administered with water or saline, exhibited 1-2% plasma bioavailability. Dean et al. also disclose at Table 1, compound 2302, when administered with bile salt alone exhibited 11% bioavailability. However, compound 2302, when administered with bile salt plus fatty acids, exhibited 14.6% bioavailability (see Table 1). In this regard, bile salt and fatty acids each individually enhance bioavailability of an active substance upon administration and delivery to a mucosal membrane. Therefore, the bile salt and the fatty acid administered with compound 2302 in Table 2 both represent a "plurality of carrier particles" and thus anticipate claims 26 and 27.

Therefore Dean et al. anticipate claims 26 and 27.

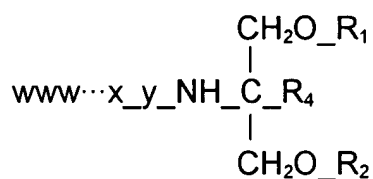
In the previous Office Action mailed April 6, 2005, claims 26 and 27 were rejected under 35 U.S.C. 102(b) as being anticipated by Lockett et al. [WO 97/25339]. **This rejection is maintained** for the reasons of record set forth in the previous Office Action mailed April 6, 2005.

Response to Arguments

At the outset, Applicants in their Response filed July 6, 2005, mistakenly identify this rejection as a 35 U.S.C. 102(a) rejection, where it is in fact a 35 U.S.C. 102(b) rejection. It is noted that the rejection against claims 26 and 27, as being anticipated by Lockett et al. [WO 97/25339], is a 35 U.S.C. 102(b) rejection. In response to this rejection, Applicants argue that Lockett et al. does not anticipate the claims because claims 26 and 27 recite a multi-particulate formulation comprising a "plurality of carrier particles". Applicants argue that Lockett et al. does not teach or suggest a formulation comprising a plurality of carrier particles and thus does not anticipate the present claims.

Applicant's arguments have been fully considered but are not found persuasive because as discussed above, while the instant specification discloses examples of carrier particles, these examples are merely *preferred* but not *required* by the instant claims. Further, the Examiner disagrees that Lockett et al. does not teach a "plurality of carrier particles" as argued.

The instant specification at page 3, paragraph [0010] discloses, "Carrier particles according to the present invention include a variety of particle-forming substances". The instant specification at page 3, paragraph [0010] also discloses, "Preferred carrier particles are those which enhance bioavailability of biologically active substance upon administration and delivery to a mucosal membrane". The instant specification at page 3, paragraph [0011] further discloses, "Preferred particle-forming substances include poly-amino acids; polyimines; polyacrylates; dendrimers...". Lockett et al. disclose a composition and methods for delivery of nucleic acids of the following formula:



where w is a nucleic acid, x is a non-amino acid or non-peptide nucleic acid binding group, and y is a spacer having a chain length equivalent to 1-30 carbon-carbon single covalent bonds. Lockett et al. also disclose, "The nucleic acid binding group may be a polyamine such as spermine, a polyimine or a dendrimer" (see page 4, lines 20 and 21). Further, Lockett et al. disclose, "the spacer "y" may also include functional domains... e.g. sugars, receptor ligands, polysaccharides, or peptides" (see page 4, lines 22-25). It is well known in the art that certain polysaccharides enhance bioavailability. For example, Yamamura et al. (Biol Pharm Bull, 1995 Vol. 2:337-341) teaches glycyrrhizin, a sulphated polysaccharide, dramatically enhances bioavailability in rats following intraperitoneal administration (see Abstract). In this instance, the

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polyimine [x group] and the polysaccharide [y group] taught by Lockett et al. both represent a "plurality of carrier particles" and thus anticipate claims 26 and 27.

Therefore Lockett et al. anticipate claims 26 and 27.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

tcg

August 23, 2005



ANDREW WANG
SUPERVISORY PATENT EXAMINER
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